

REMARKS

I. Status of the Claims

Claims 1-50 were filed with the application. Claims 2, 8, 10, 12 and 21-50 have been canceled. Claims 1, 3-7, 9, 11 and 13-20 are pending and stand rejected under 35 U.S.C. §103. The specific grounds for rejection, and applicants' response thereto, are set out in detail below.

II. Rejections Under 35 U.S.C. § 103(a)

A. *Baldini and Streckert*

Claims 1, 3-7, 9, 11 and 13-20 stand rejected under §103(a) as being unpatentable over Baldini *et al.* in view of Streckert *et al.* Baldini is cited as teaching administration of pravastatin, an HMG-CoA reductase inhibitor, to HIV-infected individuals. Streckert teaches a similarity in the protease cleavage sites of HIV gp160 and the RSV fusion protein. From this, the examiner concludes that it would be obvious to use HMG-CoA reductase inhibitors to treat RSV infections. Applicants respectfully traverse.

In order to establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference (or references when combined) must teach or suggest all the claim limitations. *Manual of Patent Examining Procedure* §2142. See also *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 2d 1438 (Fed Cir. 1991) (emphasizing that the teaching or suggestion to make the claimed combination and the reasonable expectation of success must be both found in the prior art, and

not based on appellant's disclosure). As explained below, at least (1) and (2) above are missing from this rejection.

Here, there is no logical connection between the administration of an HMG-CoA reductase inhibitor by Baldini, and the comparison of HIV gp160 with the RSV fusion protein. Indeed, Baldini was treating hyperlipidemia induced by HIV therapy, and there was no indication, nor contemplation, that pravastatin would have any effect on the HIV in the infected subjects. Thus, there is no basis for one to suggest that the skilled artisan would have read Baldini as *treating* HIV, and thus no basis for even thinking of other viruses. Moreover, even if there were some connection between the HMG-CoA reductase inhibitor and a treatment of the virus (as opposed to a side effect of a drug), there is nothing of record to suggest that such a treatment had anything to do with viral surface glycoproteins. Thus, the extrapolation to RSV is further (and completely) unwarranted.

This is a classic example of "hindsight reconstruction" which is not permitted under the law. *W.L. Gore Assoc., Inc. v. Garlock, Inc.*, 220 USPQ 303, 312-313 (Fed. Cir. 1983) ("To imbue one of ordinary skill in the art with knowledge of the invention in suit, where no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher"). There is absolutely no connection between the teachings of Baldini and Streckert justified by anything like a logical scientific rationale. As such, this rejection is completely improper and should be withdrawn.

B. Murillas in view of Streckert

Claims 1, 3-7, 9, 11 and 13-20 stand rejected as obvious over Murillas *et al.* in view of Streckert. Murillas is cited as teaching administration of atorvastatin, an HMG-CoA reductase

inhibitor, to HIV-infected individuals. Streckert teaches a similarity in the protease cleavage sites of HIV gp160 and the RSV fusion protein. From this, the examiner concludes that it would be obvious to use HMG-CoA reductase inhibitors to treat RSV infections. Appellants respectfully traverse.

This is precisely the same rejection as above, with the substitution of Murillas for Baldini. As such, it suffers from the same defects as the previous rejection, namely, that (a) there is no connection made between the use of an HMG-CoA reductase inhibitor and treatment of the viral infection, and (b) there is no connection made between the effects of an HMG-CoA reductase inhibitor and HIV gp160, and hence no basis for implicating RSV. Again, this is a classic example of hindsight reconstruction, and as such, it is improper. Reconsideration and withdrawal of this rejection also is improper.

C. Maziere in view of Streckert and Mills

Claims 1, 3-7, 9, 11 and 13-20 stand rejected as obvious over Maziere *et al.* in view of Streckert and Mills. Maziere is cited as teaching that an HMG-CoA reductase inhibitor inhibits HIV-1 *in vitro*, and Mills is cited as teaching that ribavarin can be used to treat RSV. Streckert is cited as above. Once again, applicants traverse.

As explained above with respect to the preceding rejections, the examiner has attempted to link the HIV teachings to RSV using the Streckert reference. Admittedly, Streckert teaches that there is a homology between the RSV fusion protein and HIV gp160. However, what is missing is the rational by which *this particular parameter* was selected for comparison. Where in the record is there any teaching that Maziere's HMG-CoA reductase inhibitor is acting, in any way, through a viral glycoprotein? Applicants submit that there is none. Put another way, why has the examiner ignored the many *differences* between HIV and RSV? It is pure hindsight on

the part of the examiner to pick and choose among the many characteristics of HIV and RSV, deciding upon one in particular, without any scientific evidence or reasoning whatsoever, that supports her position. Thus, again, like the previous rejections, the record is devoid of the necessary motivation to support a *prima facie* case of obviousness. Thus, reconsideration and withdrawal of the rejection is respectfully requested.

III. Conclusion

It is respectfully submitted, in light of the above, that all of the pending claims are in condition for allowance. Reconsideration and withdrawal of each of the pending rejection is, therefore, respectfully requested. A telephone call to the undersigned is invited should there be any questions regarding this paper.

Please date stamp and return the enclosed postcard to evidence receipt of this document.

Respectfully submitted,



Steven L. Highlander
Reg. No. 37,642
Attorney for Applicants

FULBRIGHT & JAWORSKI L.L.P.
600 Congress Avenue, Suite 2400
Austin, Texas 78701
(512) 536-3184

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